UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO MEDICAL MONITORING PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

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I. INTRODUCTION

Plaintiffs' motion asks the Court to play the role of a doctor and public health regulator by certifying an unprecedented medical monitoring class, holding a bench trial, and then overseeing a complex medical screening program that they characterize as "injunctive relief." The program Plaintiffs propose would include tests that some class members are already receiving due to their age, tobacco use, or medical/family histories—and that other class members should not undergo because the tests would pose more risks to them than benefits. Further, there is no conceivable justification for Plaintiffs' monitoring claims against the Mylan and Aurobindo Defendants, as well as some portions of claims against the Teva and Pharmacy Defendants, because the Court has limited Plaintiffs' theories regarding the nitrosamines found in their products to pancreatic cancer, which cannot be detected early by diagnostic testing.

Plaintiffs' two proposed classes—one advancing substantive medical monitoring claims and a second seeking monitoring relief under traditional product liability theories—fail virtually every prong of Rule 23 because they include numerous individuals with differing backgrounds, medical and family histories, lifestyles, valsartan regimens, and risk factors for various cancers. In addition, each of Plaintiffs' two classes is subject to multiple states' disparate laws, including states that have unequivocally rejected similar medical monitoring claims. Moreover, Plaintiffs' class definitions are not ascertainable, and they propose utterly unmanageable trials. For these reasons, discussed further below, Plaintiffs' motion should be denied.

II. BACKGROUND

This multi-district litigation arises from voluntary recalls of valsartan, alone or in combination with other anti-hypertensive drugs (collectively, "valsartan-containing drugs" or "VCDs") that began in July 2018. Between July 2018 and January 2019, VCDs were recalled due to the presence of trace amounts of N-Nitrosodimethylamine ("NDMA") and N-

Nitrosodiethylamine ("NDEA"). Given the very low risk of any injury that might occur from nitrosamine exposure in VCDs, the U.S. Food and Drug Administration ("FDA") emphasized at the time that patients should continue taking their VCDs because the risk of not taking them "greatly outweighs the potential risk of exposure to trace amounts of nitrosamines."[1] In addition, European regulators stated that there was no evidence to support "cancer screening or additional monitoring of patients exposed to N-nitrosamines" in valsartan, explaining:

> First, the **theoretical** risk of cancer was very low and was itself **based on a worst-case scenario**. Second, the screening methods themselves **carry risks for patients**. Third, there was **considerable uncertainty** as to which organs or tissues could be at risk from cancer.[2]

Plaintiffs move to certify two medical monitoring classes. The first—a 28-state class—seeks to assert medical-monitoring causes of action, MM Br. 6; ECF 1709, MMMC ¶ 538, even though many of the states included in the class do not recognize stand-alone medical monitoring claims. *See* App. A 3-28. The second proposed class seeks to recover medical monitoring as a form of relief for product liability claims under the laws of 49 states and territories. Both classes are defined to include individuals "who consumed a sufficiently high Lifetime Cumulative Threshold [LCT] of NDMA, NDEA, or other nitrosamine, in generic valsartan-containing drugs manufactured by or for Defendants . . . since January 1, 2012." MM Br. 6; MMMC ¶ 539. According to Plaintiffs, the following disparate combinations of VCDs, dosages, and durations satisfy the requirement of "sufficiently high LCT":

> (A) at a dose of 320 mg, the class member needs to have taken a combination of three (3) months of ZHP API, OR 18 months of Hetero API, OR 54 months of Mylan and/or Aurobindo API; (B) at a dose of 160 mg, the class member needs to have taken a combination of six (6) months of ZHP API, OR 32 months of Hetero

[1] *See* Statement on the Agency's Ongoing Efforts to Resolve Safety Issue with ARB Medications (Aug. 28, 2019), https://www.fda.gov/news-events/press-announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications.

[2] Ex. 106, European Medicines Agency, Lessons Learnt From Presence of N-nitrosamine Impurities in Sartan Medicines, 9 ("EMA Lessons Learnt") (emphases added).

> API, OR 108 months of Mylan and/or Aurobindo API; (C) at a dose of 80 mg, the class member needs to have taken a combination of 12 months of ZHP API, OR 64 months of Hetero API, OR 216 months of Mylan and/or Aurobindo API; and (D) at a dose of 40 mg, the class member needs to have taken a combination of 24 months of ZHP API, OR 128 months of Hetero API, OR 432 months of Mylan and/or Aurobindo API . . . .

MMMC ¶ 541; *see also* MM Br. 8-9.

The NDMA and NDEA content of different VCDs "varied widely across different manufactured lots of valsartan API, even from the same manufacturer, and . . . many lots of valsartan API contained levels of NDMA and/or NDEA that were either below the limits of detection or below the FDA threshold of Acceptable Daily Intake (ADI)."[3] Patients also have different non-VCD-related risk factors for cancers (e.g., tobacco use and occupational exposure to carcinogens), which Plaintiffs ignore.[4] And as Plaintiffs' own expert confirmed, doctors base medical testing decisions on ***patient***-specific inquiries, including "how sick they are, the comorbidities, [and] patient's desires themselves."[5] Nonetheless, Plaintiffs propose an identical monitoring program for all proposed class members, that would supposedly "monitor for cancers [allegedly] linked to NDMA and NDEA exposure." Memorandum of Law in Support of the Medical Monitoring Plaintiffs' Motion for Class Certification, (Dkt. 1750) ("MM Br.") at 17.

III. LEGAL STANDARD

The standard governing class certification is set forth in Defendants' Opposition to Plaintiffs' Motion for Class Certification of Consumer Economic Loss Claims (the "Consumer Opposition brief" or "Consumer Opp. Br."), incorporated herein. Plaintiffs seek to certify their proposed medical monitoring classes not only under Rule 23(b)(3), but also Rule 23(b)(2), which permits a class action where "the party opposing the class has acted or refused to act on grounds

[3] Ex. 202, Suppl. Expert Report of Lewis A. Chodosh ("Chodosh Rep.") ¶ 20, Jan. 12, 2022.
[4] Ex. 190, Expert Rebuttal Report of Dr. David Chan ("Chan Rep.") ¶ 86, Jan. 12, 2022.)
[5] Ex. 50, Dep. of Edward H. Kaplan ("Kaplan Dep.") 51:19-52:11, Jan. 19, 2022.

that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." Fed. R. Civ. P. 23(b)(2). "[T]o merit certification under section (b)(2), Plaintiffs must show that [Defendants'] conduct or refusal to act is generally applicable to the class and that the relief they seek is primarily injunctive." *Rowe v. E.I. duPont de Nemours & Co.*, No. 06-cv-1810, 2008 WL 5412912, at *10 (D.N.J. Dec. 23, 2008) (citation omitted). The hallmark of certification under Rule 23(b)(2) is cohesiveness. *See Hohider v. United Parcel Serv., Inc.*, 574 F.3d 169, 184 (3d Cir. 2009) (reversing Rule 23(b)(2) class certification because court could not reach a finding of class-wide liability and relief without undertaking individualized inquiries). The "presence of 'disparate factual circumstances'" defeats cohesiveness under Rule 23(b)(2) and forecloses a putative class action. *See Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 143 (3d Cir. 1998) (quoting *Geraghty v. U.S. Parole Comm'n*, 719 F.2d 1199, 1205-06 (3d Cir. 1983)); *see also In re St. Jude Med., Inc.*, 425 F.3d 1116, 1122 (8th Cir. 2005) (similar).

A class can only be certified under Rule 23(b)(3) if it satisfies the predominance and superiority requirements. "[I]ndividual issues, such as exposure, causation and the need for medical monitoring" generally preclude certification of 23(b)(3) medical monitoring classes. *See Gates v. Rohm & Haas Co.*, 655 F.3d 255, 264 (3d Cir. 2011); *see also Sanders v. Johnson & Johnson, Inc.*, No. 03-2663, 2006 WL 1541033, at *4 (D.N.J. June 2, 2006) ("differences" in state laws governing medical monitoring may swamp any common issues and defeat predominance").

IV. ARGUMENT

The Court should deny Plaintiffs' motion because their class proposals are rife with individualized legal and factual issues that preclude a finding of cohesiveness/predominance or superiority. The putative medical monitoring class is a diverse nationwide group of individuals with widely varied (i) NDMA/NDEA exposure levels, (ii) medical histories, including cancers,

and (iii) existing health care and screening. No court has ever certified a class with so much legal or factual variance. In addition, Plaintiffs' class proposals also fail to satisfy the ascertainability requirement of Rule 23 because of the difficulties of determining class membership.

A. Plaintiffs' Class Proposals Fail Rules 23(b)(2), 23(b)(3), and 23(a)(3).

Although the Third Circuit has not determined whether medical monitoring claims should be assessed under Rule 23(b)(2) or (b)(3), the better approach is to consider the propriety of such classes under Rule 23(b)(3). *See Gates*, 655 F.3d at 262 ("[W]e question whether the kind of medical monitoring sought here can be certified under Rule 23(b)(2) but we do not reach the issue."). This is so because Rule 23(b)(2) "was 'designed specifically for civil rights cases seeking broad declaratory or injunctive relief for a numerous and often unascertainable or amorphous class of persons.'" *Barnes*, 161 F.3d at 142 (citation omitted); *see also, e.g.*, *Zinser v. Accufix Res. Inst., Inc.*, 253 F.3d 1180, 1195, *amended by* 273 F.3d 1266 (9th Cir. 2001) (recognizing that "[a] request for medical monitoring cannot be categorized as primarily equitable or injunctive *per se*"). By contrast, medical monitoring cases essentially seek money for medical testing. *See Boughton v. Cotter Corp.*, 65 F.3d 823, 827 (10th Cir. 1995) (affirming rejection of medical monitoring class under Rule 23(b)(2) because "the relief sought was primarily money damages"). Here, regardless of whether the Court applies Rule 23(b)(2) or (b)(3), Plaintiffs' class proposals fail because: (1) the law governing medical monitoring varies significantly from state to state; and (2) the proposed classes implicate highly individualized factual evidence.

1. Legal Variations Preclude a Finding of Predominance or Cohesiveness.

It is well established that nationwide medical monitoring class actions are not certifiable due to fundamental "[d]ifferences in state laws on medical monitoring." *See, e.g.*, *In re St. Jude*, 425 F.3d at 1122 (reversing certification); *Sanders*, 2006 WL 1541033, at *6 (recognizing state

law variance with respect to medical monitoring); *Almond v. Janssen Pharms., Inc.*, 337 F.R.D. 90, 100 (E.D. Pa. 2020) (granting motion to strike nationwide medical monitoring class under both Rule 23(b)(3) and 23(b)(2); "a fault line divides class members whom state law permits to seek relief through a no-injury medical monitoring claim, and those whom state law prohibits from asserting the very claim at issue here"); *In re NHL Players' Concussion Injury Litig.*, 327 F.R.D. 245, 260, 266 (D. Minn. 2018) (denying class certification of medical monitoring claims because "individualized legal issues will substantially predominate over common legal issues"); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 74 (S.D.N.Y. 2002) (noting that variations in state law are particularly inimical to class treatment of medical-monitoring claims because many state supreme courts have never addressed medical monitoring, and courts faced with such proposals are thus placed in "the undesirable position of attempting to predict how their courts of last resort would resolve that issue"); *In re Prempro Prods. Liab. Litig.*, 230 F.R.D. 555, 569 (E.D. Ark. 2005) ("The fact that medical monitoring is not treated uniformly throughout the United States creates a myriad of individual legal issues that may swamp any possible cohesion in a 23(b)(2) class.") (citation omitted). These ample authorities mirror recent pronouncements by the Council of the American Law Institute that the law governing medical monitoring is a "fractured landscape." Reporters' Note at 302, Council Draft No. 2 of the Restatement (Third) of Torts, Concluding Provisions; *see also* Comment to Draft No. 2 at 291.

Plaintiffs' proposed 28-state class asserting independent medical monitoring causes of action ("Independent Cause-of-Action Class" or "ICA") and 49-state and territory class asserting negligence, product liability, and other substantive claims that seek medical monitoring as a form of relief ("Remedy Class") do not address this problem. Plaintiffs argue that their proposed "class structure reflects the one arguably meaningful difference between and among the laws of the

different states: some states permit medical monitoring as an independent claim, while others only permit medical monitoring as a remedy for an underlying claim." MM Br. 7. This is a gross understatement of the variations among relevant state laws.

ICA Class. As a threshold matter, Plaintiffs include numerous states within the ICA Class even though those states have never recognized such a cause of action. *See* App. A 3-28. For example, state appellate courts in Missouri and Nevada have rejected medical monitoring as an independent claim. *See, e.g.*, *Moore v. Scroll Compressors, LLC*, 632 S.W.3d 810, 819 (Mo. Ct. App. 2021) ("Missouri law does not recognize medical monitoring as a separate cause of action."); *Badillo v. Am. Brands, Inc.*, 16 P.3d 435, 441 (Nev. 2001) ("[W]e hold that Nevada common law does not recognize a cause of action for medical monitoring."); *Sadler v. PacifiCare of Nev.*, 340 P.3d 1264, 1271 (Nev. 2014) (discussing "medical monitoring as a remedy, rather than a cause of action"). Similarly, a Vermont federal court has described medical monitoring as a form of injunctive relief as opposed to a cause of action. *Sullivan v. Saint-Gobain Performance Plastics Corp.*, 431 F. Supp. 3d 448, 451 (D. Vt. 2019) ("The court analyzes the availability of medical monitoring as a form of injunctive relief available (or not) under existing Vermont law, not as a new cause of action."). And the New York Court of Appeals has rejected medical monitoring as an independent cause of action, where there is no proof of present physical injury. *See Caronia v. Philip Morris USA, Inc.*, 5 N.E.3d 11, 18 (N.Y. 2013).

In addition, although Plaintiffs identify Arizona as a state whose residents fall within the ICA Class, it is "unclear" whether medical monitoring "is a form of damages or a stand-alone cause of action in Arizona." *In re NHL*, 327 F.R.D. at 262 (*comparing Arch v. Am. Tobacco Co.*, 175 F.R.D. 469, 481 (E.D. Pa. 1997), *with Quiroz v. ALCOA Inc.*, 382 P.3d 75, 79 (Ariz. Ct. App. 2016)). Plaintiffs also incorrectly designate Iowa and New Hampshire as ICA states considering

this Court's statement that those jurisdictions "have either not, or inconsistently, ruled on allowing an independent medical monitoring claim." Dkt. 838 at 33. The same is true of Alaska, Idaho and Hawaii, as none of those states have "any court decisions that clearly address the issues related to medical monitoring." *In re NHL*, 327 F.R.D. at 262 (no on-point caselaw from these states).

Plaintiffs also lump numerous other jurisdictions into their proposed class simply because a federal court predicted that the state would recognize medical monitoring at some point in the future. But a federal court "may not act as a judicial pioneer" in setting state law in areas where the state courts have not weighed in. *Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 253 (3d Cir. 2010) (quotations omitted). Moreover, Plaintiffs' categorizations ignore federal court decisions holding that certain states would ***not*** recognize an independent medical monitoring cause of action. *See, e.g., In re Zantac (Ranitidine) Prods. Liab. Litig.*, No. 20-MD-2924, 2021 WL 2682659, at *9 (S.D. Fla. June 30, 2021) (dismissing medical monitoring claims brought on behalf of Montana citizens because the state supreme court had not commented on the issue); *Cole v. ASARCO, Inc.*, 256 F.R.D. 690, 695 (N.D. Okla. 2009) (holding that "Oklahoma law does not support creation of a medical monitoring class"); *Rosmer v. Pfizer, Inc.*, Case No. CIV.A. 9:99–2280, 2001 WL 34010613, at *5 (D.S.C. 2001) (noting that "[a] fundamental flaw with Plaintiff proceeding to represent a medical monitoring class is the fact that South Carolina has not recognized a cause of action for medical monitoring."); *Pickrell v. Sorin Grp. USA, Inc.*, 293 F. Supp. 3d 865, 868 (S.D. Iowa 2018) ("This Court finds that the Iowa Supreme Court would be unlikely to adopt a medical monitoring cause of action rooted in a negligence theory, especially absent an actual injury."). In short, Plaintiffs' ICA Class includes states whose laws do not recognize medical monitoring causes of action. This alone requires denial of the proposed class.

Even if Plaintiffs' designations were accurate, their classes would still fail because they

ignore other material variations within the jurisdictions that purportedly recognize stand-alone claims for medical monitoring. *See* App. A 3-28. For example:

- *Necessary showing of injury*. As previously discussed, some states, such as New York, require proof of present physical injury to recover for medical monitoring. *See Caronia*, 5 N.E.3d at 18. At least one state permits medical monitoring claims only upon a showing that the plaintiff has suffered a subcellular or subclinical injury. *See Donovan v. Philip Morris USA, Inc.*, 914 N.E.2d 891, 901-02 (Mass. 2009). By contrast, in other states, including Florida, Pennsylvania, Utah, and West Virginia, medical monitoring is an independent cause of action that does not require present injury. *See Fiorentino v. Cabot Oil & Gas Corp.*, No. 3:09-CV-2284, 2011 U.S. Dist. LEXIS 126314, at *11-12 (M.D. Pa. Oct. 31, 2011) (citing *Redland Soccer Club, Inc. v. Dep't of Army*, 696 A.2d 137, 145-46 (Pa. 1997)); *Petito v. A.H. Robins Co.*, 750 So. 2d 103 (Fla. Dist. Ct. App. 2000); *Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 979 (Utah 1993); *Acord v. Colane Co.*, 719 S.E.2d 761, 770 (W. Va. 2011).

- *Whether a treatment for the disease exists.* In Utah, the plaintiff must show that a treatment exists that can alter the course of the illness. *See Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 979 (Utah 1993). Conversely, other states, such as Pennsylvania, do not require plaintiffs to show that a treatment currently exists. *See Redland Soccer Club*, 696 A.2d at 146 n.8.

- *Nature of available detection procedures*. Some of the states identified by Plaintiffs as recognizing independent medical monitoring claims (e.g., Florida, Massachusetts) require a plaintiff to prove the existence of a procedure that provides early detection of the disease for which medical monitoring is sought. *See Petito*, 750 So. 2d at 106-07; *Donovan*, 914 N.E.2d at 902. Other jurisdictions do not appear to impose such a prerequisite. *Meyer ex rel. Coplin v. Fluor Corp.*, 220 S.W.3d at 717-18 (Missouri)[6]; *Burns v. Jaquays Mining Corp.*, 752 P.2d 28, 33-34 (Ariz. Ct. App. 1987) (Arizona).

Remedy Class. Plaintiffs also ignore significant legal variations within the Remedy Class, which encompasses individuals from "every state, territory, and possession[] of the United States," excluding only Mississippi.[7] As with the ICA Class, the Remedy Class includes individuals from states that do not permit relief absent present physical injury (e.g., Alabama and Kentucky) and

[6] As discussed above, a recent decision by Missouri Court of Appeals found that Missouri law does not recognize medical monitoring as an independent claim. *Moore*, 632 S.W.3d at 819.

[7] Plaintiffs' inclusion of North Carolina in their proposed Remedy Class contravenes this Court's prior ruling, which dismissed medical monitoring claims with prejudice under North Carolina law on the ground that "North Carolina has rejected outright an independent medical monitoring claim as well as a medical monitoring claim as the measure of damages." Dkt. 838 at 34.

those that do (e.g., California and Maryland). *See* App. A 29-48.

Moreover, Plaintiffs' proposed Remedy Class encompasses individuals from numerous states where the law regarding medical monitoring is unclear or in flux. *See id*. For example, the Sixth Circuit has described Tennessee law on medical monitoring as "murky." *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 575 n.7 (6th Cir. 2005). The state of medical monitoring claims and remedies in Connecticut is also unclear. *See Dougan v. Sikorsky Aircraft Corp.*, 337 Conn. 27, 42-43, 251 A.3d 583, 593-94 (2020) ("[W]e will assume, ***without deciding***, that Connecticut law recognizes a claim for subclinical cellular injury that substantially increased the plaintiffs' risk of cancer" and "we also assume, ***without deciding***, that the [the elements that apply in Massachusetts] govern proof of a medical monitoring claim" in this state) (emphases added). The same is true with respect to Delaware, Indiana, Georgia, and Nebraska. *See* App. A 6, 32-33, 39-40. "[C]onsiderations of comity and federalism counsel that [federal courts] proceed gingerly when venturing into uncharted waters of state substantive law." *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1251 (11th Cir. 2013). The lack of authoritative judicial pronouncements regarding medical monitoring is a principal reason why courts have rejected class proposals just like Plaintiffs' here. *See In re NHL*, 327 F.R.D. at 266 ("Many states never have recognized a claim for medical monitoring, a circumstance that would force this [c]ourt into the undesirable position of attempting to predict how their courts of last resort would resolve that issue.") (citations omitted).

In addition, state laws vary with respect to:

- *Whether medical monitoring relief is limited to toxic tort cases*. In *Ayers v. Township of Jackson*, 525 A.2d 287, 298 (N.J. 1987), the New Jersey Supreme Court held that medical monitoring expenses may be awarded based on the risk of future disease caused by exposure to pollutants. However, the New Jersey Supreme Court has since clarified that medical monitoring is not a legitimate form of relief in product liability/prescription drug cases. *See Sinclair v. Merck & Co.*, 948 A.2d 587, 591, 594-95 (N.J. 2008). Similarly, Missouri—which, contrary to Plaintiffs' assertion, only recognizes medical monitoring as a remedy—has limited that form of recovery to toxic

tort cases. *See Ratliff v. Mentour Corp.*, 569 F. Supp. 2d 926, 928-29 (W.D. Mo. 2008) ("[I]n Missouri, medical monitoring claims are available in toxic tort cases" only and not in "garden variety product liability cases"). *See also* App. A.

- *Proof that a monitoring procedure exists that makes detection of the disease possible*. Some of the states included in Plaintiffs' Remedy Class (e.g., Maryland) require proof "that monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial." *Exxon Mobil Corp. v. Albright*, 71 A.3d 30, 82, *modified in part on other grounds*, 71 A.3d 150 (Md. 2013). By contrast, other states (e.g., California) have not expressly addressed whether plaintiffs must prove that an effective detection method exists. *See Potter v. Firestone Tire & Rubber Co.*, 863 P.2d 795, 825 (Cal. 1993). *See also* App. A.

Finally, Plaintiffs do not address the widely varying state laws—previously recognized by this Court—that govern the underlying negligence, product liability and other substantive claims asserted by their Remedy Class. *See, e.g.*, Dkt. 818 at 10. ("It is nearly an unassailable conclusion that the laws of the fifty states with respect to some of the causes of actions will conflict and affect the outcome of the case."); App. B. For example, "[t]he law of negligence, including subsidiary concepts such as duty of care, foreseeability, and proximate cause" differs among the states in "important" ways that preclude nationwide class certification. *In re Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1300 (7th Cir. 1995); *see also In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1085 (6th Cir. 1996) (granting petition for writ of mandamus and directing trial court to decertify nationwide class; "[i]f more than a few of the laws of the fifty states differ, the district judge would face an impossible task of instructing a jury on the relevant law"); *Norwood v. Raytheon Co.*, 237 F.R.D. 581 (W.D. Tex. 2006) (denying certification of proposed nationwide class asserting negligence claim; although "the basic elements of a negligence cause of action are consistent throughout the United States, there are substantial variations in negligence law from one jurisdiction to the next").

These state law variances preclude certification. In some states, such as Colorado, foreseeability is "an integral element" of the duty of care assessment. *Westin Operator, LLC v. Groh*, 347 P.3d 606, 613-14, n.5 (Colo. 2015). By contrast, two states (Iowa and New Mexico)

have adopted the Restatement (Third) of Torts: Liability for Physical Harm § 7(a), which eliminates foreseeability from the duty analysis and presumes that parties have "a duty to exercise reasonable care when the actor's conduct creates a risk of physical harm." *Thompson v. Kaczinski*, 774 N.W.2d 829, 835 (Iowa 2009); *Rodriguez v. Del Sol Shopping Ctr. Assocs., L.P.*, 326 P.3d 465, 467 (N.M. 2014). As this Court recognized, "[e]ven a cursory review of the law" with respect to negligent misrepresentation and negligence *per se* "confirms" that the applicable laws vary in material respects for these claims as well. Dkt. 818 at 10. "For instance, under New York's law for negligent misrepresentation a plaintiff is required to show either privity of contract between the parties or a relationship approaching privity, while Texas does not require such a showing." *Id.* (citations omitted). Similarly, some states limit negligence *per se* claims to statutes containing express private rights of action, and others do not. *See id.* Further, states have varying requirements related to causation. *See, e.g., Alarcon v. Alcolac Inc.*, 488 S.W.3d 813, 828 (Tex. App. 2016) ("To establish substantial factor causation in the absence of direct evidence of causation, the plaintiff must prove with scientifically reliable expert testimony that the plaintiff's exposure to the defendant's product more than doubled the plaintiff's risk of contracting the disease.").

In short, myriad legal variations would overwhelm any common legal issues, precluding predominance and cohesiveness. For this reason alone, the Court should deny Plaintiffs' motion.

2. Factual Variations Preclude a Finding of Predominance, Cohesiveness and Typicality.

Individualized factual questions and issues also preclude certification, including facts pertaining to causation, the extent of class members' exposures, their need for medical monitoring, and the costs associated with that monitoring. *See, e.g., Lafferty v. Sherwin-Williams Co.*, No. CV11706321, 2018 WL 3993448, at *6 (D.N.J. Aug. 21, 2018) (medical monitoring class certification precluded where "individual fact finding is essential to determine whether one of these

hazardous substances impacted someone," and proposed class members' "potential exposures, if any, are likely drastically different."). Courts routinely deny certification of medical monitoring claims for similar reasons, under both Rule 23(b)(3) and (b)(2). *See, e.g.*, *Gates*, 655 F.3d at 267 (denying class certification of medical monitoring claims under both Rule 23(b)(2) and Rule 23(b)(3) because "the inquiries into whether class members were exposed above background levels, whether class members face a significantly increased risk of developing a serious latent disease, and whether a medical monitoring regime is reasonably medically necessary all require considering individual proof of class members' specific characteristics"); *Barnes*, 161 F.3d at 143 (similar); *Rowe*, 2008 WL 5412912, at *13 (denying class certification of medical monitoring class under both Rule 23(b)(2) and (b)(3) because "the elements of significant exposure, increased risk of disease, and necessity of medical monitoring pose numerous individualized issues").[8] Courts have applied similar reasoning in finding the typicality requirement of Rule 23(a)(3) lacking as well. *See, e.g.*, *In re Baycol Prods. Liabl. Litig.*, 218 F.R.D. 197, 205 (D. Minn. 2003) (finding medical monitoring and other claims "involve individual issues such as injury, causation, the learned intermediary doctrine, and comparative fault," which defeated typicality); *Blaz v. Galen Hosp. Ill., Inc.*, 168 F.R.D. 621, 625 (N.D. Ill. 1996) (similar). Plaintiffs' proposal presents many of the same individualized fact issues.

(a) Plaintiffs' Claims Implicate Highly Individualized Causation Inquiries.

While causation standards vary among states, most states' laws require plaintiffs to

[8] *See also, e.g.*, *In re St. Jude*, 425 F.3d at 1122-23 (reversing certification of a medical monitoring class because a "myriad of individual issues," including "each plaintiff's need (or lack of need) for medical monitoring"); *Barraza v. C.R. Bard, Inc.*, 322 F.R.D. 369, 390 (D. Ariz. 2017) (similar); *Rhodes v. E.I. du Pont de Nemours & Co.*, 253 F.R.D. 365, 380 (S.D. W. Va. 2008) (similar); *In re Prempro*, 230 F.R.D. at 569-70 (similar).

establish that defendants' alleged conduct was the "but for" cause of their alleged injuries. *See Williams v. Johnson & Johnson*, No. 1:20-CV-00544-MSM-LDA, 2022 U.S. Dist. LEXIS 10889, *7-8 (D.R.I. Jan. 18, 2022). In states that allow medical-monitoring claims or relief ***absent*** present physical injury, plaintiffs must still demonstrate that the defendants' alleged conduct "caused each [class member] to have a significantly increased risk of contracting serious latent diseases." *Barnes*, 161 F.3d at 145; *Caronia v. Philip Morris USA, Inc.*, No. 06-CV-224 (CBA) (SMG), 2011 U.S. Dist. LEXIS 12610, at *35-37 (E.D.N.Y. Jan. 12, 2011) (plaintiffs must prove that the defendant's "tortious conduct is what caused them . . . to require medical monitoring"), *aff'd in part*, 715 F.3d 417 (2d Cir. 2013). The need for "individual proof" of causation precludes class certification under both Rule 23(b)(3) and (b)(2). *Gates*, 655 F.3d at 264, 270.

The causation inquiry here is necessarily individualized because exposure to carcinogens can occur through a wide range of environmental factors, including "lifestyle factors (e.g., nutrition, tobacco and alcohol use, physical inactivity), naturally occurring exposures (e.g., ultraviolet light, radon gas, infectious agents), medical treatments (e.g., radiation, chemotherapy, hormone drugs, drugs that suppress the immune system), workplace exposures, household exposures, and pollution." Chan Rep. ¶ 83. Notably, nearly half of the personal-injury plaintiffs in this MDL have a smoking history according to their fact sheets. As Dr. Ursina Teitelbaum, Clinical Director of the Penn Pancreatic Cancer Research Center has explained, even assuming that exposure to NDMA or NDEA through VCDs was a cancer risk factor, age, occupational exposure to carcinogens and smoking are far more significant risk factors.[9] Thus, individualized issues predominate with respect to whether "proposed class members were exposed to other known

[9] Ex. 201, Expert Report of Ursina R. Teitelbaum ("Teitelbaum Rep.") 5, Jan. 12, 2022, at 6-7 (older age is the "greatest known risk factor" for pancreatic cancer . . . Tobacco usage remains the leading risk factor for developing lung cancer [.]").

carcinogens that pose a far greater risk of cancer than NDMA and NDEA." Chan Rep. ¶ 87.

(b) Whether Class Members Have Been Exposed to "Sufficiently High" Levels of NDMA/NDEA Through VCDs Is Highly Variable.

The fundamental tenet of toxicology is that "the dose makes the poison." *Lipitor (Atorvastatin Calcium) Mktg. v. Pfizer, Inc.*, 892 F.3d 624, 639 (4th Cir. 2018). Here, although Plaintiffs have posited "Lifetime Cumulative Thresholds" ("LCTs") in an attempt to group class members together, the reality is that putative class members had vastly different exposures to NDMA/NDEA, depending on their dose, duration of exposure and which company's VCDs they used. This, too, defeats predominance, because a jury would have to separately determine each plaintiff's level of exposure and whether it sufficed to merit recovery. *See, e.g.*, *Rowe*, 2008 WL 5412912, at *17 (denying certification where there was "no proof of common significant exposure among the class[.]"). Plaintiffs' LCTs do not solve this problem, even if they had scientific merit, which Plaintiffs have not been able to demonstrate.

Plaintiffs assume that every batch of every valsartan product from the same manufacturer contained identical amounts of NDMA or NDEA."[10] That is not the case. "NDMA and NDEA content of different valsartan products varied widely across different manufactured lots of valsartan API, even from the same manufacturer." Chodosh Suppl. Rep. ¶ 20. Importantly, "many lots of valsartan API contained levels of NDMA and/or NDEA that were either below the limits of detection or below the FDA threshold of Acceptable Daily Intake (ADI)." *Id.* As a result, even assuming that exposure to NDMA or NDEA in VCDs were capable of causing cancer, "the incremental cancer risk will vary considerably across patients who consumed affected valsartan due to variability in valsartan dosage and duration of therapy, variability in NDMA and NDEA impurity across valsartan manufacturers, and variability across lots within valsartan

[10] Ex. 200, Report of Karla V. Ballman ("Ballman Rep.") 7, Jan. 12, 2022.

manufacturers." Chan Rep. ¶ 88. Thus, even ignoring alternative risk factors such as food, alcohol and tobacco, disparate exposures to NDMA and NDEA in VCDs by class members presents additional individualized questions and issues that defeat cohesion and predominance. In short, if Plaintiffs' proposed medical monitoring claims and remedies were tried in a single class proceeding, one jury would have to determine which risks entitle class members to surveillance and which do not— a highly individualized exercise that defeats both predominance and cohesion.

(c) Whether the Proposed Medical Monitoring Is Medically Necessary or Appropriate for Each Class Member Is Highly Individualized.

States that recognize medical monitoring as a claim or remedy generally require proof that the proposed monitoring is medically necessary—i.e., that the program is "different from that normally recommended in the absence of exposure." *Barnes*, 161 F.3d at 146 (citation omitted). But, what is medically necessary varies significantly from person to person. Chan Rep. ¶¶ 41-47; Teitelbaum Rep. 3-8. Notably, Plaintiffs' expert, Dr. Kaplan, conceded that his "plan is a guideline, just like the NCCN has their guidelines, and it's up to the individual practitioner to -- to decide based on the individual patient what is appropriate for them." Kaplan Dep. 126:12-22.

The Third Circuit has "been skeptical that the necessity for individuals' medical monitoring regimes can be proven on a class basis," *Gates*, 655 F.3d at 268, because "[i]n order to prove the program he requires, a plaintiff must present evidence about his individual [medical] history and subject himself to cross-examination by the defendant about that history." *Barnes*, 161 F.3d at 146; *Arch v. Am. Tobacco Co.*, 175 F.R.D. 469, 489 (E.D. Pa. 1997) ("This factor alone would require an individual, plaintiff-by-plaintiff comparison.").

These principles further preclude cohesion and predominance because, as Plaintiffs' own expert acknowledged, treatment decisions (e.g., the necessity of medical screening) are based on the "patient's specific situation." Kaplan Dep. at 52:7-8, 51:19-52:11 (When "deciding on

treatment for the patient," Dr. Kaplan considers, *inter alia*, "how functional and how sick they are, the comorbidities, [and] the patient's desires:). Plaintiffs nevertheless propose a one-size-fits-all monitoring program for every class member who satisfies the proffered LCTs. For example:

Plaintiffs' proposed monitoring ignores patients' medical histories, including existing screening. Factors other than valsartan use—age, medical history such as diabetes, heart failure or myocardial infarction, lifestyle, and smoking history—are far more important in the individualized assessment of whether cancer screening is appropriate. Chan Rep. ¶¶ 62, 64-65, 67, 69. Indeed, because so many people are exposed to carcinogens or have other risk factors for cancer, they will already be undergoing many of the screenings specified by Plaintiffs. *Id.* ¶ 71 ("In the MEPS data, out of the 128 patients who took an affected valsartan in 2018, were 50 years or older, and were asked whether they had a colonoscopy, 74.2 percent reported that they received a colonoscopy in the past 10 years."); *see also* Teitelbaum Rep. 17 ("[P]atients taking VCDs are typically older and so would likely be already receiving the recommended cancer tests."). Smokers, for example, may already be undergoing low dose helical CT scans, one of the tests Plaintiffs' expert, Dr. Edward Kaplan, recommends for the medical-monitoring program. *Id*. 7.

In addition, a significant number of the proposed class members may already be at an increased risk of colon cancer due to age and other risk factors and are therefore already undergoing colonoscopies. *Id.* at 22. For example, [redacted]. [11] [redacted]. *Id.* at 194:2–197:15. [redacted]

[11] Ex. 33, Dep. of John Judson 17:7–18:1; 45:15–45:24; 194:2–194:22, Feb. 8., 2021.

[redacted]. *Id.* at 194:14-22. [redacted][12] As these examples illustrate, the need for medical monitoring is a "highly individualized" inquiry that depends on each "patient's medical history . . . the patient's personal choice, and other factors." *In re St. Jude*, 425 F.3d at 1122; *see also Barraza*, 322 F.R.D. at 382. Crucially, unlike tobacco, "NDMA and NDEA are not identified as a risk factor or a carcinogen by any cancer organization or screening guidelines taskforces." Teitelbaum Rep. 17. The only screening for exposure to carcinogenic substances recommended by the U.S. Preventive Services Task Force is for lung cancer, and that recommendation is specifically limited to smokers who are between ages 55 and 80 and who have at least a 20-year pack history.[13]

Plaintiffs' proposed monitoring does not account for potential harm to class members as a result of screening. The potential for negative health risks of medical monitoring is another individualized issue that precludes certification of claims like those here. *Gates*, 665 F.3d at 269; *see also, e.g.*, *Barraza*, 322 F.R.D. at 383 (similar with respect to CT-scan); *Arch*, 175 F.R.D. at 490 (denying certification of medical monitoring class where "the physician would not recommend the medical monitoring procedure" for some class members). As Dr. Chan explains, "proposed class members may have underlying conditions that preclude them from screening and thus, would not be subject to medical monitoring; proposed class members may be too old for effective cancer treatments and thus, might not be subject to medical monitoring; and proposed class members may

[12] Ex. 34, Dep. of Paulette Silberman, 54:21–55:1, 93:18–24, March 22, 2021.
[13] Ex. 212, Dep. of Ursina R. Teitelbaum, M.D. ("Teitelbaum Dep.") 68:15-21, Mar. 10, 2022.

face more harm than benefits from the medical monitoring." Chan Rep. ¶ 77. Indeed, procedure risk is a "very real concern" with the tests themselves, particularly for older patients (i.e., the VCD-prescribed population), who have "increased risk of complications" from invasive screening methods such as endoscopy and biopsy, as well as potentially unnecessary radiation exposure from imaging. Teitelbaum Rep. 16, 18. Indeed, the architect of Plaintiffs' proposed monitoring program, Dr. Kaplan, concedes that there are numerous risks associated with the screening procedures he recommends here. Kaplan Dep. 71:1-11; 73:6-74:7. Further, cancer screenings can adversely impact patients by generating "anxiety, overdiagnosis, and complications from invasive cancer workups." Teitlebaum Rep. 8. Although "[t]he bulk of anxiety is associated with more invasive procedures such as screening colonoscopy," *Id*. merely telling a patient that he or she is at increased risk of cancer would "engender a lot of anxiety and fear" of cancer. Teitelbaum Dep. 40:7-12. Accordingly, there are pervasive individual factual issues that preclude certification.

Plaintiffs' proposal ignores variations in the need for and availability of screening based on the type of VCD each proposed class member used. Whether Plaintiffs' proposed screening program would provide any possible benefit to proposed class members will also vary based on the particular VCDs to which they were exposed. As Defendants have explained, VCDs manufactured by Mylan or Aurobindo (or by Teva using Mylan API) did not contain NDMA above the FDA's acceptable daily intake limits. *See* Consumer Opp. Brief at 8-9, 13-14. Rather, they only contained NDEA—and this Court has already excluded Plaintiffs' experts' opinions that NDEA can cause ***any cancer other than pancreatic***. *Daubert* Order 1, Dkt. 1958. As a result, the only cancer that could potentially warrant monitoring among patients who used these manufacturers' products is pancreatic cancer. Defendants do not believe their VCDs can cause pancreatic cancer but, even if they could, there is no reliable screening method for pancreatic

cancer in asymptomatic individuals. Teitelbam Dep. 91:71-96:20. Thus, Plaintiffs' medical monitoring proposal would not provide any benefit to proposed class members who used Mylan's and Aurobindo's VCDs. For this reason, too, the propriety of Plaintiffs' proposed monitoring will necessarily vary from one proposed class member to the next, and class certification as to Mylan and Aurobindo (and any Defendant in their respective chains of distribution) should be denied.

(d) Variability of Services and Costs in the Proposed Medical Monitoring Class

Plaintiffs have also failed to establish that a common methodology can be used to determine healthcare spending for Plaintiffs' proposed medical monitoring program. *See Georgine v. Amchem Prods.*, 83 F.3d 610, 632 (3d Cir. 1996) ("problems created by differences in medical monitoring costs" defeat the typicality and commonality requirements of Rule 23). To the contrary, there is "wide variability in services and costs and uncertainty in estimating the necessary services and costs for an unspecified time in the future." Chan Rep. ¶ 15. Moreover, the evidence suggests that some portion of the proposed class members would refuse to undergo the as-offered monitoring services, making it all the more impossible to estimate the cost of Plaintiffs' proposals. *Id.* ¶ 72. Further, because certain putative class members might already be screening for cancers due to other underlying conditions, there is no incremental cost increase associated with their screenings here; indeed, these class members would already be undergoing those screenings anyway. *Id.* ¶ 73. Notably, Plaintiffs' expert, Dr. Song, admits that "the cost of monitoring for each patient will vary substantially due to variation in a number of key factors, including 'the insurer mix, site of care composition, and network status of the providers for the patient population.'" *Id.* ¶ 99 (quoting Song Rep. ¶ 39). Despite this concession, Dr. Song nevertheless "simply assumes that all proposed class members would receive the same medical monitoring tests and procedures, and that prices of those tests and procedures would reflect the broad average of Medicaid,

Medicare, and commercial insurer prices." *Id.* But "any effort to estimate the aggregate cost of monitoring would require collecting individualized data on every proposed class member" for (i) whether they would be indicated for monitoring in the absence of the use of affected valsartan; (ii) whether they would be indicated for monitoring in the presence of the use of affected valsartan, and (iii) the details of their insurance arrangement. *Id.* ¶ 100. Accordingly, a multitude of questions specific to each proposed class member would become necessary, thereby foreclosing the argument that such information could be determined using a common methodology.

3. Class Certification Is Not The Superior Method And Would Result In An Unmanageable Trial.

Rule 23(b)(3) requires that a class action be "superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). Superiority is lacking where a putative class trial would not be manageable, *i.e.*, where "there are simply too many individual issues and class members" for a trial to be "workable." *Arch*, 175 F.R.D. at 492; *see also Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 618 (3d Cir. 1996) ("[W]e do not see how an action of this magnitude and complexity could practically be tried as a litigation class."). Although Rule 23(b)(2) does not contain a superiority element, courts have repeatedly made clear that manageability is an essential requirement of cohesiveness. *See Barnes,* 161 F.3d at 143 (Rule 23(b)(2) classes must be cohesive and not "unmanageable") (citations omitted); *See also, e.g., Sanders v. Johnson & Johnson, Inc.*, No. CIV. 03-2663, 2006 WL 1541033, at *10 (D.N.J. June 2, 2006) (similar); *Lightfoot v. District of Columbia*, 273 F.R.D. 314, 337 (D.D.C. 2011) (similar).

Plaintiffs' proposals entirely fail the test of manageability and efficiency. Determining who is a member of the proposed classes would be a herculean undertaking, even assuming it were possible, requiring a series of mini-trials on the amounts of NDMA and NDEA to which each putative class member was supposedly exposed, in light of the variability of NDMA and NDEA

among manufacturers and even in different lots of the same product. Likewise, minitrials would be required to determine class membership given Plaintiffs' exclusion of individuals who allegedly developed cancer as a result of taking Defendants' VCDs. A trial on the merits would be even more unmanageable. As discussed above, Plaintiffs' Independent Cause-of-Action class implicates the medical monitoring laws of ***28 jurisdictions***, whereas the Remedy Class would be governed by the widely varying laws of ***49 states*** and every federal territory and possession. In addition, each class member would "have to demonstrate his/her specific exposure, how that exposure has increased his/her risk of disease, and his/her corresponding need for medical monitoring, all of which would require medical expert testimony specific to each individual." *Rowe*, 2008 WL 5412912, at *21. The result would be an endless series of mini-trials on what non-VCD risk factors each class member has (e.g., smoking); what (if any) levels of NDMA/NDEA each class member has been exposed to through VCDs; and whether the proposed medical monitoring is medically necessary for each class member, which would require a foray into each class member's medical history. Moreover, unless Plaintiff Silberman was excluded from the trial, CVS's defense to her claims would necessarily require a lengthy mini-trial on successor liability issues relating to CVS's "file-buy" of prescription records from a now-closed pharmacy.[14]

[14] Plaintiffs do not seek to certify a medical monitoring class against CVS on any basis *other* than Paulette Silberman's claims. But Silberman never filled or purchased valsartan at a CVS store, and instead purchased valsartan at a pharmacy within a Quick Chek grocery store in Passaic, New Jersey that later transferred its prescription records to CVS as part of a file-buy asset acquisition and pharmacy closure. *See* Ex. 34, Deposition of P. Silberman, at 49 ("It was always QuickChek."); *see also id.* at 131-132. Plaintiffs insist that because CVS produced copies of Silberman's records with CVS branding, CVS must have acquired Quick Chek's liabilities. Plaintiffs are simply wrong, both factually, *see* Ex. 78, Declaration of Thomas Moffatt, and legally. Generally, "when a company sells its assets to another [entity], the acquiring company is not liable . . . simply because it has succeeded to the ownership of the assets of the seller." *Lefever v. K.P. Hovnanian Enters.*, 160 N.J. 307, 310 (N.J. 1999). Regardless, a medical monitoring class cannot be certified against CVS because Silberman is an atypical and inadequate plaintiff due to the unique defense to her claims. *See In re Schering Plough Corp. ERISA Litig.*,

Plaintiffs' purported trial plan does not address these concerns. First, the plan is based on a false premise, *i.e.*, that medical monitoring is an equitable remedy such that "a bench trial is appropriate for all aspects of it, or, at the very minimum, for the determination of the plan itself." MM Br., Ex. G at 2. As Plaintiffs acknowledge, the *Barnes* court indicated that the question of entitlement to medical monitoring would be submitted to the jury—an outcome that was later obviated by the court's decertification of the proposed class and affirmance by the Third Circuit. *See id.* (citing *Barnes v. Am. Tobacco Co.*, 989 F. Supp. 661, 668-69 (E.D. Pa. 1997)); *see also Barnes*, 161 F.3d 127. Moreover, *Barnes* acknowledges that other courts "have repeatedly sent medical monitoring claims to a jury." 989 F. Supp. at 668-69.

Plaintiffs' medical monitoring trial would also violate Defendants' Seventh Amendment rights. Plaintiffs propose a trifurcated trial, with phase 1 focusing on whether medical monitoring is warranted, phase 2 addressing the feasibility and structure of the proposed program, and phase 3 centering on the apportionment of program costs. *See* MM Br., Ex. G at 1-4. In the first proposed phase, Plaintiffs appear to propose that a jury or the Court simply rubberstamp the findings on the liability issues that would have already been resolved in the initial economic loss trial. *See id.* at 2 ("[T]he jury's findings on the liability merits in the Economic Loss Trial as to fraud and warranty . . . would also facilitate . . . conclusions as to the same issues."). In other words, under Plaintiffs' plan, two separate juries would be tasked with addressing overlapping questions with regard to Defendants' alleged conduct, in violation of the Seventh Amendment. *See, e.g., In re Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1303-04 (7th Cir. 1995) (decertifying proposed issues class because "[t]he first jury ... will determine merely whether one or more of the defendants was

589 F.3d 585, 598 (3d Cir. 2009) ("[R]equirement that the proposed representatives not be subject to unique defenses"); *Hanon v. Dataproducts Corp.*, 976 F.2d 497, 508 (9th Cir. 1992) (class certification denied where typicality requirements not met due to defenses unique to plaintiff).

negligent," which "overlaps" with the issues to be resolved "in individual follow-on litigation," creating a "looming infringement of Seventh Amendment rights"); *In re ConAgra Peanut Butter Prods. Liab. Litig.*, 251 F.R.D. 689, 698-99 (N.D. Ga. 2008) (rejecting issues class because "the risk that a second jury would have to reconsider the [common] liability issues decided by the first jury is too substantial") (citation omitted). Moreover, the economic loss Plaintiffs' Trial Plan is itself utterly unmanageable. *See* Consumer Opp. Brief, Argument at § II.

Plaintiffs also assert that increased risk "will be demonstrated by common evidence in the form of expert testimony on general causation." MM Br., Ex. G at 3. But, as previously discussed in Part IV.A, "'[c]ausation in the air' is not enough"—i.e., general causation does not suffice. *In re Prempro*, 230 F.R.D. at 570. Plaintiffs must establish that "defendants' intentional or negligent [conduct] caused each ***individual*** [class member] to have a significantly increased risk of contracting serious latent diseases thereby demonstrating the need for medical monitoring." *Barnes*, 161 F.3d at 145 (emphasis added); *see also In re Prempro*, 230 F.R.D. at 570. Although Plaintiffs have proposed a *de minimis* NDMA/NDEA LCT of 1,962 ug to trigger medical monitoring, *see* Madigan Rep. (MM Br., Ex. B), such a generalized threshold does not address whether a particular plaintiff "has suffered an actual increased risk of disease" that warrants medical monitoring—which will necessarily "differ depending on his/her background risk of disease" and underlying medical history. *See Rowe*, 2008 WL 5412912, at *18 (rejecting attempt to prove that all class members were at an increased risk of developing diseases based on consumption of drinking water containing perfluorinated materials at a level higher than .02 ppb for at least a year because whether each proposed class member was exposed to that level of perfluorinated materials (and whether it is associated with a risk of injury) will vary based on individual weight and water consumption habits).

Plaintiffs' proposed second and third trial phases—which focus on feasibility and structure of the program and allocation of costs, respectively—would also be highly unmanageable. Even if Plaintiffs were correct that such issues should be decided by the Court (as opposed to a jury), they do not articulate a manageable way to try them in a single proceeding. As the Third Circuit has recognized, "[a]lthough the general public's monitoring program can be proved on a classwide basis, an individual's monitoring program by definition cannot." *Barnes*, 161 F.3d at 146; *see also Gates*, 655 F.3d at 268. Thus, resolution of the feasibility and necessity of medical monitoring must be patient-specific, involving the presentation of evidence regarding each class member's "individual" circumstances. *Id.* Given the sheer number of potential class members, their risk factors and individual medical histories, there is no manageable mechanism to address these fundamental elements of Plaintiffs' medical monitoring claims and remedies on a class basis.

Plaintiffs alternatively propose that, at least for phases 1 and 2, the Court "embed aspects of the medical monitoring trial into the Economic Loss Trial," which Plaintiffs claim "could be accomplished while avoiding jury confusion." MM Br., Ex. G at 4. However, as previously discussed, the law governing medical monitoring "is greatly varied," *In re NHL*, 327 F.R.D. at 260, which would add an additional layer of legal complexity to the already-unworkable 121-subclass, 52-state, 5-theory economic loss trial. Moreover, jurors would have to juggle all of the thorny issues related to the economic loss claims (e.g., the contention that valsartan is worthless) with the separate and equally complex questions of exposure, increased risk of cancer and suitability of medical monitoring for individual class members. Plaintiffs do not—and cannot—provide any manageable mechanism to try these highly complex and patient-specific questions simultaneously before a single jury in one proceeding. Because Plaintiffs have failed to propose a feasible trial plan, class treatment is not superior, and the Court should deny Plaintiffs' motion.

4. Plaintiffs' Cases Are Inapposite And/Or Contrary To Third Circuit Law.

Although Plaintiffs cite a few cases in which courts have certified medical monitoring claims, those cases are either inapposite or clear outliers. For example, in *Baker v. Sorin Group Duetschland GMBH*, No. 1:16-cv-00260, 2017 U.S. Dist. LEXIS 235430, at *3 (M.D. Pa. Oct. 23, 2017) (cited in MM Br. 10, 14), the court certified a medical monitoring class of patients who were allegedly exposed to nontuberculous mycobacterium ("NTM") through a Sorin 3T Heater-Cooler System ("3T System") used to regulate their blood temperature during open heart surgeries performed at two Pennsylvania hospitals. In so doing, however, the court made clear that "[t]he putative class claim [was] highly distinguishable from" the one deemed uncertifiable by the Third Circuit in *Gates*, "where exposure varied based on time, activity level, age, sex, genetic make-up, work, travel, and recreational habits." *Id.* at *30 (citing *Gates*, 655 F.3d at 267). In other words, *Baker* not only involved a single, discrete latent disease but also uniform classwide exposure and few (if any) alternative risk factors for the condition in question. *See id.* Moreover, the court reasoned that the essential element of medical necessity could be proven on a classwide basis because the CDC had already sent out "notices that suggest that *all* patients exposed to the 3T System receive medical monitoring." *Id.* at *32. Neither circumstance is present here. For one thing, unlike in *Baker*, class members had varying exposures to NDMA/NDEA, are highly diverse based on non-VCD-related risk factors, and the dose, duration of exposure and which company's valsartan they were exposed to. And in further contrast to *Baker*, no public health agency recommended screening for VCD users, and at least one agency has actually discouraged it, underscoring the inherently individualized nature of the proof required to establish class members' entitled to medical monitoring. *See* EMA Lessons Learnt, 9.

Plaintiffs' other authorities—*In re Diet Drugs Prods. Liabl. Litig.*, No. 98-20626, 1999

WL 673066 (E.D. Pa. Aug. 26, 1999), and *In re Telectronics Pacing Sys., Inc.*, 172 F.R.D. 271, 275 (S.D. Ohio 1997) (cited in MM Br. 10-11)—are "rare exceptions" and contravene more recent Third Circuit law. *See In re Fosamax Prods. Liab. Litig.*, 248 F.R.D. 389, 396 & n.8 (S.D.N.Y. 2008) (describing *Diet Drugs* and *Telectronics* as the rare "exceptions"; "Lower courts almost unanimously have rejected class certification in pharmaceutical products liability actions, including those seeking medical monitoring for a heightened risk of future injury, because the proposed class actions failed to satisfy many of Rule 23's requirements."). Both cases predate the Third Circuit's decision in *Gates*, which recognized that medical monitoring is generally not susceptible to classwide treatment precisely because "causation and medical necessity often require individual proof." *Gates*, 655 F.3d at 264. Moreover, even assuming that Plaintiffs' cases were still good law, they would still not support Plaintiffs' arguments here. After all, *Diet Drugs* involved a scenario in which multiple governmental agencies and medical organizations had formally endorsed monitoring, *see In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 147 (E.D. La. 2002) (distinguishing *Diet Drugs* on this basis), and *Telectronics* featured the unique circumstance in which the defendant "acknowledge[d] that ***all*** implantees [of the allegedly defective pacemaker] require[d] medical monitoring." 172 F.R.D. at 287 (emphasis added). Neither of those circumstances is present here, rendering Plaintiffs' cases inapposite.

B. Plaintiffs' Proposed Classes Are Not Ascertainable.

Plaintiffs' proposal also flunks the ascertainability requirement for class certification, as interpreted by the Third Circuit. "A plaintiff does not satisfy the ascertainability requirement if individualized fact-finding or mini-trials will be required to prove class membership." *Carrera v. Bayer Corp.*, 727 F.3d 300, 307 (3d Cir. 2013). The onus is on Plaintiffs to identify a "reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition." *Hayes v. Wal-Mart Stores, Inc.*, 725 F.3d 349, 355 (3d Cir. 2013); *see also*

Afzal v. BMW of N. Am., LLC, No. 15-cv-8009, 2020 WL 2786926, at *10 (D.N.J. May 29, 2020) (citation omitted). To define a class, Plaintiffs must "propose a method of proving the proper point where exposure to [a potentially harmful chemical] presents a significant risk of developing a serious latent disease for each class member." *Gates*, 655 F.3d at 268. The Court in *Gates* recognized that a regulatory threshold is not a "proper standard for determining liability under tort law." *Id*. at 267-68. Instead, Plaintiffs must specify a defined level of exposure where there exists a significant risk of developing a disease. *Id.*

Here, Plaintiffs' proposed medical monitoring classes are limited to those individuals who consumed certain thresholds of NDMA and NDEA. MMMC ¶ 541; *see also* MM Br. 8-9. In addition to the reasons discussed in the Consumer Opp. Brief at 71-75, which are incorporated herein, Plaintiffs' proposed medical monitoring class definitions fail for three reasons. ***First***, VCD manufacturer, dose, and duration of use are not a reliable metric for determining how much NDMA or NDEA each individual actually ingested. Rather, there was significant variability in the amounts of NDMA and NDEA between different lots from the same manufacturer. Chodosh Rep. ¶ 20.

Second, there is no easily obtainable, objective information identifying (i) how much VCD was actually ingested or (ii) the levels of NDMA or NDEA in each pill. Plaintiffs argue that the information necessary to identify class members is readily available through pharmacy and prescription records that identify the API manufacturer, their respective National Drug Code ("NDC") codes, the dose of valsartan prescribed, and the duration of time the putative class member used valsartan. MM Br. 9. But these records are not readily obtainable from tens of thousands of independent pharmacies. *See* Consumer Opp. Brief at 73-74. Moreover, in so arguing, Plaintiffs assume that each putative class member consumed all of his or her prescription valsartan, even though the general population only "adheres" to a daily regimen of prescription medication

50% of the time. Teitelbaum Dep. 60:2-6, 304:3-17. Indeed, the recall likely caused many class members to discontinue VCD's prior to finishing their dispensed prescription. More fundamentally, neither NDC codes nor any of the other information Plaintiffs tout provide the lot and batch numbers associated with each prescription, which are necessary to determine "whether the proposed class members in fact consumed their prescribed valsartan, and, if so, whether the consumed valsartan contained an NDMA and/or NDEA impurity." Ballman Rep. 6-7; Chodosh Rep. ¶ 15 (because NDC codes do not specify lot number, "it cannot possibly be the case that Plaintiffs' proposed algorithm could determine whether any Plaintiff had exceeded the Lifetime Exposure to NDMA and/or NDEA that Plaintiffs have proposed to define class membership"). At most, the NDC codes merely reflect that an individual filled a prescription for VCDs at a particular dosage, which is not a reliable basis for ascertaining satisfaction of Plaintiffs' LCT and ultimate membership in the classes. The difficultly of applying Plaintiffs' LCT criteria to determine class membership is evidenced by the fact that Plaintiffs are unable to identify the amount of exposure for their named class representatives, instead leaving placeholders in the operative third amended pleading. MMMC ¶¶ 12-28. If Plaintiffs cannot calculate the lifetime cumulative exposure for their class representatives, they cannot do it for millions of class members. Moreover, of the 14 plaintiffs identified in Plaintiffs' class certification motion, MM Br. 20, Plaintiffs subsequently dismissed at least two of them (Kenneth Berkson and Richard O'Neill) because they did not meet Plaintiffs' own LCT for inclusion in the class. Dkts. 1829, 1913.

Third, Plaintiffs' LCTs were not reliably derived through science. Plaintiffs cite to two experts—Drs. Panigrahy and Madigan—to support their proposed LCTs. MM Br. 4, 16. Notably, neither Dr. Panigrahy nor Dr. Madigan submitted a supplemental expert report for class certification. Rather, Plaintiffs rely solely on their prior reports at the general causation stage to

support their LCTs. This is significant because neither Dr. Panigrahy nor Dr. Madigan offers a single opinion in his report regarding LCTs. To the contrary, Dr. Panigrahy opined that ***there is no bright line threshold*** for NDMA or NDEA carcinogenicity. MM Br., Ex. C, Panigrahy Rep. 90. Because Plaintiffs' experts did not perform an LCT analysis, Plaintiffs rely upon sleight of hand rather than scientific evidence. For instance, Plaintiffs do not disclose the assumed amount of NDMA/NDEA impurity in a 320mg tablet. Ballman Rep. 13. Likewise, the LCTs needed to reach a meaningful increased cancer risk for each type of alleged cancer are not provided by Madigan or Panigrahy. *Id.* at 14. Instead, "there are multiple [LCTs] referenced in the Madigan and Panigrahy reports, and multiple different levels of NDMA and/pr NDEA impurity associated with each manufacturer and each manufacturer's lot/batch." *Id.* Without these specified values, Defendants—and the Court—are left to guess at how Plaintiffs' proposed LCTs were derived. This unscientific approach cannot form the basis for class membership.

C. Plaintiffs Cannot Certify a Medical Monitoring Class as to Wholesaler Defendants For Additional Reasons.

Plaintiffs' Wholesaler-specific medical monitoring classes cannot be certified for two additional reasons. First, as set forth in the Wholesaler Defendants' Opp. Brief, which is incorporated herein, Plaintiffs do not and cannot demonstrate standing to assert medical monitoring claims against the Wholesalers. Second, Plaintiffs' Wholesaler-specific medical monitoring classes are not ascertainable because Plaintiffs' reliance on NDC numbers to identify potential class members who may have been prescribed a VCD distributed by a Wholesaler is insufficient and has been rejected—and the data Plaintiffs would require to accurately identify medical monitoring class members do not exist. For these reasons, too, Plaintiffs' motion should be denied.

V. CONCLUSION

For the reasons set forth above, Plaintiffs' motion for class certification should be denied.

Dated: April 12, 2022

Respectfully submitted,[15]

By: */s/ Clem C. Trischler*

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[15] This brief is being submitted on behalf of the Manufacturer and Wholesaler Defendants, as well as Pharmacy Defendants CVS, Express Scripts, and Walmart. Plaintiffs have dismissed claims against Pharmacy Defendants Rite Aid Corporation and Walgreen Co., Dkt. 1880, though the Court has not entered the proposed order filed by Plaintiffs. Following the Court's initial Motion to Dismiss Orders, Plaintiffs omitted Pharmacy Defendants Humana Pharmacy, Albertson's, Kroger, and OptumRx from their amended medical monitoring complaint, Dkt. 1709, and accordingly do not assert medical monitoring claims against those Defendants.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 12, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Frank H. Stoy
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